

NOV 24 2009

510(k) SUMMARY

Lanx Posterior Cervicothoracic Spinal Fixation System

Submitter Information

Name and Address: Lanx, Inc.
 390 Interlocken Crescent, Suite 890
 Broomfield, CO 80021

Contact Person: Andrew Lamborne

Date Prepared: August 26, 2009

Device Identification

Proprietary Name: Lanx Posterior Cervicothoracic Spinal Fixation System (PCFS)

Common Name: Spinal Fixation System

Classification: MNI - 21 CFR 888.3070 - Pedicle Screw Spinal System
 KWP - 21 CFR 888.3050 - Spinal Interlaminar Fixation Orthosis

Predicate Device Information

K071905	Lanx PCFS	Lanx, Inc.
K030197	Ascent PCS	Blackstone Medical, Inc.
K042508	Summit/Mountaineer OCT	Depuy Spine, Inc.

Intended Use / Indications for Use

When intended to promote fusion of the occipito-cervico-thoracic region of the spine (occiput-T3) in skeletally mature patients, the Lanx Posterior Cervicothoracic Spinal Fixation System is indicated for the following:

- Degenerative Disc Disease (as defined by neck and back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
- Spondylolisthesis
- Spinal Stenosis
- Trauma/Fracture/Dislocation
- Atlanto-Axial Fracture with Instability
- Occipito-Cervical Dislocation
- Failed Previous Fusion
- Tumor

The use of occipital bone screws is limited to placement in the occiput only.

The use of polyaxial screws is limited to placement in the upper thoracic spine (T1-T3) in treating thoracic conditions only. They are not intended to be placed in the cervical spine.

Technological Characteristics

The Lanx Posterior Cervicothoracic Spinal Fixation System consists of various titanium alloy screws, hooks, plates, rods, connectors, etc. that are used to build a construct to provide supplemental stabilization of spinal segments to support fusion. The system components can be assembled in a variety of configurations, allowing the surgeon to tailor the construct to the particular needs of the patient.

Performance Data

Performance testing and engineering analysis was conducted to characterize the performance of the Lanx Posterior Cervicothoracic Spinal Fixation System. The device functioned as intended and the observed test results demonstrate substantial equivalence to the predicate devices.

Substantial Equivalence

The Lanx Posterior Cervicothoracic Spinal Fixation System has the same or similar intended use, indications, technological characteristics, and principles of operation as the predicate systems. Mechanical testing also demonstrated comparable mechanical properties to the predicate devices. Thus, the Lanx Posterior Cervicothoracic Spinal Fixation System is substantially equivalent to the predicate devices.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

Lanx, Inc
% Mr. Andrew Lamborne
390 Interlocken Crescent, Suite 890
Broomfield, Colorado 80021

NOV 24 2009

Re: K092656

Trade Name: Lanx Posterior Cervicothoracic Spinal Fixation System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminar fixation orthosis
Regulatory Class: Class II
Product Code: KWP, MNI
Dated: August 26, 2009
Received: August 28, 2009

Dear Mr. Lamborne:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please

go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucml15809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Mark N. Melkerson
Director Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K092656

Device Name: Lanx Posterior Cervicothoracic Spinal Fixation System

Indications for Use:

When intended to promote fusion of the occipito-cervico-thoracic region of the spine (occiput-T3) in skeletally mature patients, the Lanx Posterior Cervicothoracic Spinal Fixation System is indicated for the following:

- Degenerative Disc Disease (as defined by neck and back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
- Spondylolisthesis
- Spinal Stenosis
- Trauma/Fracture/Dislocation
- Atlanto-Axial Fracture with Instability
- Occipito-Cervical Dislocation
- Failed Previous Fusion
- Tumor

The use of occipital bone screws is limited to placement in the occiput only.

The use of polyaxial screws is limited to placement in the upper thoracic spine (T1-T3) in treating thoracic conditions only. They are not intended to be placed in the cervical spine.

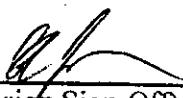
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of Surgical, Orthopedic,
and Restorative Devices

Page 1 of 1

510(k) Number K092656

Pg 1 of 1